IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE ADOLOR CORPORATION SECURITIES LITIGATION	:	CIVIL ACTION NO. 04-1728

SURRICK, J. **MAY 8, 2009**

MEMORANDUM

Presently before the Court is Defendants' Motion to Dismiss Plaintiffs' Amended Class Action Complaint in its Entirety. (Doc. No. 42.) For the following reasons, the Motion will be granted.

I. BACKGROUND

Adolor ("Adolor" or "the Company") is a bio-pharmaceutical company engaged in the development of pharmaceutical products for the treatment of pain. (Doc. No. 40 ¶ 2 (hereinafter, "Am. Compl.").) In the early 2000s, Adolor's lead product was a drug called Entereg, also known as alvimopan, which Adolor developed to treat post-operative ileus ("POI"), a serious complication that occurs in connection with abdominal and other surgeries. (*Id.* ¶¶ 3-4.) POI is a major cause of post-surgical death for which there was no Food and Drug Administration approved treatment at the time. (*Id.* ¶ 4.) In order to market and sell Entereg in the United States, Adolor had to conduct clinical trials in accordance with FDA regulations. (*Id.* ¶ 3.) The Central Laborers' Pension Fund and the Greater Pennsylvania Carpenters Pension Fund (collectively, the "Plaintiffs") filed this lawsuit against Adolor and its individual officers and

directors for making misleading public statements regarding the Entereg clinical trials.[1] The Amended Complaint contains class action claims asserted on behalf of all purchasers of Adolor Corporation Common Stock between April 2, 2003, and December 22, 2004 (the "Class Period"), and sets forth three claims for relief. The first claim alleges that Defendants violated Section 10(b) of the Securities Exchange Act of 1934, 15 U.S.C. § 78j(b), and Securities and Exchange Commission Rule 10b-5, 17 C.F.R. § 240.10b-5. The second claim alleges that Defendants violated Section 20(a) of the Exchange Act, 15 U.S.C. § 78t(a). The third claim alleges that the Individual Defendants violated Section 11 of the Securities Act of 1933 ("Securities Act"), 15 U.S.C. § 77k.[2]

Plaintiffs contend that statements made by Defendants regarding the results of a series of four clinical trials for Entereg were misleading.[3] The Company conducted the trials during Phase

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[1] For purposes of this Memorandum, we refer to Adolor and the officer and director defendants collectively as "Defendants." The Individuals Defendants are: Bruce A. Peacock, President and Chief Executive Officer of Adolor; Michael Dougherty, Senior Vice President, Chief Operating Officer, Chief Financial Officer and Treasurer of Adolor; Bruce Wallin, Vice President, Clinical Research and Development of Adolor; David Jackson, Senior Vice President, Research and Development of Adolor. The following Individual Defendants are named only for the purposes of the Section 11 claim and are members of Adolor's Board of Directors: Armando Anido; Paul Goddard; George V. Hager, Jr.; David M. Madden; Claude H. Nash; Robert T. Nelsen; and Donald E. Nickelson.

[2] There is also a related shareholder derivative suit pending under Civil Action No. 04-3469 alleging state law claims against Defendants.

[3] Obtaining regulatory approval for a new drug involves, among other things, three phases of trials that culminate in a New Drug Application ("NDA") that the manufacturer submits to the FDA. *See In re Viropharma Sec. Litig.*, No. 02-1627, 2003 WL 1824914, at *2 (E.D. Pa. April 7, 2003) (discussing the regulatory process). Phase I trials involve a small, controlled trial involving human subjects. *Id.* Phase I is conducted primarily to determine the drug's safety profile and dosage range. *Id.* In Phase II, the drug is tested on volunteer patients afflicted with the disease to test its effectiveness. *Id*. If these phases are successful, the drug is put through a final Phase III trial where the drug is tested on patients in clinics and hospitals. *Id.* Once Phase

III of the drug's development in collaboration with GlaxoSmithKline ("Glaxo") pursuant to a incentive-based Collaboration Agreement (the "Agreement").

A. The Glaxo Agreement

Adolor signed the Agreement with Glaxo in April 2002 to collaborate on the global development and commercialization of Entereg. (*Id.* ¶ 4.) Under the Agreement, Adolor received a $50 million non-refundable licensing fee from Glaxo. Adolor also stood to earn as much as $220 million in additional payments if it met certain objectives, including a $10 million bonus payment if the FDA accepted the Entereg NDA. (*Id.* ¶ 34.) Under the Agreement, Glaxo had the right to terminate the arrangement if Adolor failed to meet certain milestones, including steps in product development and regulatory events. (Doc. No. 43, Ex. 5 at 8.) Glaxo and Adolor were to divide the costs of developing and marketing Entereg, with Adolor taking responsibility for the development activities in the United States and Glaxo taking responsibility for development activities in Europe. (*Id.*) In 2002, Glaxo's payments to Adolor comprised 96% of the Adolor's total consolidated revenue. (*Id.* at 19.) By the end of the Phase III trials in 2004, Adolor and Glaxo had spent over $100 million in the research and development of Entereg. (*Id.* at 37.)

B. The Phase III Trials

Adolor had completed the first two phases of its testing of Entereg and was set to begin Phase III by the end of 2001. (*Id.* at 8.) The Phase III trials involved four different studies, three of which tested Entereg's effectiveness on patients undergoing various gastrointestinal

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III testing is complete, the drug company files an NDA with the FDA and the FDA issues one of three letters to the applicant: an "approval" letter, a "not approvable" letter, or an "approvable" letter. *Id.*

procedures, while the fourth tested only its safety. (*Id.*) The three studies dealing with the efficacy of Entereg were labeled 14CL302, 14CL313 and 14CL308 ("302," "313," and "308," respectively).[4] (Am. Compl. ¶¶ 5, 36.) These studies were to be "double-blinded," "randomized,"[5] and "placebo-based." (Am. Compl. ¶ 36 (*quoting* Adolor Corp., Annual Report (Form 10-K), at 8 (Mar. 18, 2003)).) Patients were placed into three categories, one receiving placebo, one receiving a 6 mg dosage of Entereg, and one receiving a 12 mg dosage of Entereg. (*Id.*) The information collected in the studies would be used to measure the time of recovery of gastrointestinal functions for patients at each dosage level. (*Id.*)

1. Study 302

Study 302 enrolled patients from March 2001 to December 2002 and included patients undergoing partial colectomies, simple hysterectomies, and radical hysterectomies. (*Id.* ¶ 37.) On April 2, 2003, Adolor announced the top-line results[6] for Study 302 in a press-release that stated in pertinent part:

> Adolor corporation announced today top-line results of its first Phase 3 clinical study (14CL302) for its novel product candidate, alvimopan, in the management of postoperative ileus.
>
> A statistically significant difference was achieved in the primary endpoint of the

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[4] The fourth study that tested Entereg's safety was called 14CL306. This study forms no basis for Plaintiffs' allegations.

[5] Adolor's Form 10-K filed on March 18, 2003 indicates that "[u]nder the protocols, patients [we]re randomized into three arms of approximately 150 patients each to receive placebo, 6 mg, or 12 mg doses of alvimopan." Adolor Corp., Annual Report (Form 10-K), at 35 (Mar. 18, 2003).

[6] "Top-line results" refers to the results for the entire population of the study and does not break down the results into subgroups. (*See* Am. Compl. ¶¶ 37, 44); *see also, e.g.*, Adolor Corp., Current Report (Form 8-K), Ex. 99.1 (Apr. 2, 2003).

> study, time to recovery of gastrointestinal function, in patients in the alvimopan 6 mg treatment group compared to patients in the placebo group (Coz proportional hazard model; hazard ratio = 1.47; P<0.01). Time to recovery of gastrointestinal function was a composite measure of the time to recovery of both lower and upper gastrointestinal function as defined by time to first flatus or bowel movement and time to tolerability of solid foods, whichever occurred last. A difference in favor of the alvimopan 6 mg treatment group versus placebo was observed from a secondary endpoint, including time to hospital discharge order written. A positive trend was observed in the primary endpoint of the study for the alvimopan 12 mg treatment group; however the difference from placebo was not statistically significant (Cox proportional hazard model, hazard ratio = 1.23; P = 0.11).
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> . . .
>
> "We are delighted to have completed a major milestone in our alvimopan Phase 3 clinical program in postoperative ileus. We believe the results of this study support our goal of submitting a New Drug Application for alvimopan in 2003. We look forward to completing the accrual of our additional alvimopan postoperative clinical studies, which will need to confirm the results of the study in order to file a New Drug Application," commented Bruce A. Peacock, President and Chief Executive Officer of Adolor.

(*Id.* ¶ 37 (*quoting* Adolor Corp., Current Report (Form 8-K), Ex. 99.1 (Apr. 2, 2003)).) That same day, Adolor conducted a conference call with market analysts to discuss the results. (*Id.* ¶ 38.) During the call, Adolor's Senior Vice-President of Research and Development, David Jackson, stated:

> The next two studies refer to studies 308 and 313 are similar in design to Study 302. . . . The main difference from Study 302 is in the patient population but 308 and 313 will enroll patients undergoing large or small bowel resections or radical hysterectomies. In study 308, similar to 302, simple hysterectomies are to exceed 20% of the total enrollment. Patients undergoing simple hysterectomies are not included in Study 313.

(Doc. No. 43, Ex. 11 at 8.) Afterwards, six analysts questioned Defendants about the results of Study 302. (*Id.* at 9-21.) No analyst asked why Adolor excluded simple hysterectomy patients in Study 313. (*Id.* at 9-21.) That day, Adolor's stock price closed at $12.95, up 31.34% from the

day before, on volume of 6.9 million shares.[7] (Am. Compl. ¶ 41.) The Amended Complaint

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[7] Adolor made additional public statements regarding Study 302 in its Form 10-Q for the period ending March 31, 2003, stating:

> We are highly dependent on achieving success in the clinical testing, regulatory approval and commercialization of our lead product candidate, alvimopan, which may never be approved for commercial use. If we are unable to commercialize alvimopan, our ability to generate revenues will be impaired and our business will be harmed.
>
> . . .
>
> The market price for our common stock has been highly volatile and may continue to be highly volatile in the future. The market price for our common stock is highly dependent on the results of our clinical trials, in particular our Phase III program clinical trials of alvimopan in post-operative ileus. . . . Failure of these results to be positive would adversely impact the market price of our common stock.
>
> . . .
>
> If we continue to incur operating losses for a period longer than anticipated, we may be unable to continue our operations. We believe our existing cash, cash equivalents and short-term investments as of March 31, 2003 of approximately 136.7 million will be sufficient to meet our currently estimated operating and investing requirements into mid-2005. We have generated operating losses since we began operations in November 1994. We expect to continue to generate such losses and will need additional funds that may not be available in the future. We have no products that have generated any revenue, and as of March 31, 2003, we have incurred a cumulative net loss of $166.5 million.
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> . . .
>
> Because our product candidates are in development, there is a high risk that further development and testing will demonstrate that our product candidates are not suitable for commercialization.
>
> . . .
>
> Preclinical testing and clinical testing are long, expensive and uncertain processes. Failure can occur at any stage of testing. Success in preclinical testing and early clinical testing trials does not ensure that later clinical trials will be successful.
>
> We may suffer significant setbacks in advanced clinical trials, even after promising results in earlier trials.
>
> . . .
>
> We have limited experience in conducting and managing the clinical trials necessary to obtain regulatory approval.
>
> . . .
>
> The concept of developing peripherally restricted opioid analgesics and narcotic antagonist drugs is relatively new and may not lead to commercially successful drugs.

does not allege that any of Defendants sold Adolor stock after the April 2, 2003 price increase, and the Company's public filings indicate that the Individual Defendants did not engage in any prohibited insider trading in the period leading up to or after results of Study 302 were announced.

2. Study 313

Study 313 enrolled patients from February 2002 to June 2003 and included only patients undergoing bowel resections and radical hysterectomies. (*Id.* ¶ 42.) Patients undergoing simple hysterectomies were not included in this study. On September 23, 2003, Adolor issued a press release announcing that the results of Study 313 were statistically significant at both the 6 mg and 12 mg dosage levels. *See* Adolor Corp., Current Report (Form 8-K), Ex. 99.1 (Sept. 23, 2003). Defendant Bruce Peacock then conducted a conference call with analysts and answered a number of questions concerning the use of simple hysterectomy patients in Study 313 and Study 308, including this exchange:

> Analyst: Do you think you're gonna need a confirmatory study at 12 mg to file at that dose. And if so, do you have any concerns about the confounding impact of simple hysterectomies in the other trial?
>
> Peacock: Well, I'm not sure there's a confounding impact of simple hysterectromies in the other trial. I think we haven't spoken about the information from Study 302 broken out by patient types. What we have seen in prior studies is clearly the duration of ileus in the simple hysterectomy patient is shorter than in the patient that's undergoing bowel resection surgery. However, as we've indicated before, there are patients who undergo a simple hysterectomy, who go into an extended ileus. You can't predict up front who they're going to be so we certainly believe there's a potential for alvimopan there. In terms of picking dose, again I have to go back and say, you really need to

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(Doc. No. 43, Def. Ex. 12 at 16 (emphasis omitted).)

> get all of the data from all of the studies pulled together and then sit down and make an intelligent decision about that.
> . . .
>
> Analyst: I think there was a question before about confounding data with respect to simple hysterectomies. Can you just take us through the 308 study? If I remember correctly right around the 450 patient mark or so you changed the enrollment criteria to exclude simple hysterectomy patients. Is that correct?
>
> Peacock: [O]riginally with the 450 patients we had that there wouldn't be any more than 20% of the simple hysterectomies which would get you to a number about 90. We then made a decision to, as you know, expand enrollment in that study to go from the 450 up to the 660. I'm pretty confident, David and/or Bruce, that we would expect a few simple hysterectomies to be in that additional patient group. So if that's the case, then, if you just do the simple math, it seems to me that this study is more highly powered for non-simple hysterectomy patients than the 313.
>
> Analyst: So we shouldn't be concerned at all about the confounding for simple hysterectomies?
>
> Peacock: Yeah. I would say that I think the important point there is that there, you know, we're pleased with the results from 313 with the 510 patients enrolled and as you just said there will be more bowel resection surgery patients enrolled in 308 than even what was seen in 313.

(Doc. No. 43, Ex. 10 at 16, 22). That afternoon, Adolor's stock price closed at $19.75, an increase of nearly 33%.[8] (Am. Compl. ¶ 51.) Again, the Amended Complaint does not allege

[8] Adolor followed up its public statements on September 23rd with a report of the Phase III trial in its Form 10-Q filing for the period ending September 30, 2003, which included the following statements:

> There is a risk that our clinical studies do not show a statistically significant difference between our product candidates and our placebos. In our Phase III clinical study POI 14CL302 for alvimopan in the management of POI, the 12 mg alvimopan treatment group's difference from placebo was not statistically significant. There can be no assurance that this outcome will not occur again in our further clinical testing, or that the 6 mg alvimopan treatment group will again achieve a statistically

that any Defendants sold Adolor stock after the price increased, and the Company's public filings do not indicate that the Individual Defendants engaged in any prohibited insider trading in that timeframe.

3. Adolor's Public Offering

Shortly after Adolor announced the results of Study 313, the Company made a public offering of 6 million shares of common stock that raised a total of $119 million. (Am. Compl. ¶ 52.) The details of Study 302 and Study 313 were disclosed in Adolor's Offering Prospectus, which included the following statements:

> We have completed three Phase II clinical trials studying the use of Entereg for the management of POI that frequently follows abdominal surgery in which opioids are used in pain relief. Subsequently we initiated our Entereg POI Phase III program consisting of four studies. Three of these studies (POI 14CL302, POI 14CL308 and POI 14CL313) are double-blind, placebo-controlled multi-center studies each designed to enroll patients scheduled to undergo certain types of major abdominal surgery and receiving opioids for pain relief . . . .
>
> Study 302. In April 2003, we announced top-line results of our first POI Phase III

> significant difference from placebo in our further clinical testing.
>
> The market price for our common stock has been highly volatile and may continue to be highly volatile in the future. For example, in the calendar year ended December 31, 2002, the price of our common stock reached a low of $9.09 per share in July 2002 and a high of $18.57 per share in January 2002. During the first nine months of 2003, the price of our common stock was $9.55 per share at its low point in March 2003 and $20.20 per share at its high point in September 2003.
>
> The market price of our common stock is highly dependent on the results of our clinical trials, in particular our Phase III clinical trials of alvimopan in POI. There can be no assurance that our clinical trials will be fully enrolled within expected time frames or that the results of any of our Phase III clinical trials will be positive. Failure to achieve positive results in any or all of these studies would adversely impact the market price of our common stock.

Adolor Corp., Quarterly Report (Form 10-Q), at 15 (Oct. 29, 2003).

> clinical study, Study 302. Study 302 enrolled 451 patients, and was designed to include large bowel resection patients and radical hysterectomy patients, as well as simple hysterectomy patients (22% enrolled patients). A statistically significant difference was achieved in the primary endpoint of the study, time to recovery of GI function, in patients in the Entereg 6 mg treatment group compared to patients in the placebo group. . . . A positive trend was observed in the primary endpoint of the study for the Entereg 12mg treatment group; however, the difference from placebo was not statistically significant . . . .
>
> Study 313. In September 2003, we announced top-line results of our second POI Phase III clinical study, Study 313. Study 313 enrolled 510 patients and was designed to include large bowel resection patients, small bowel resection patients and radical hysterectomy patients, and exclude simple hysterectomy patients. A statistically significant difference was achieved in the primary endpoint of the study, time to recovery of GI function, in both the Entereg 6 mg and 12 mg treatment groups compared to the placebo group . . . .

(*Id.* ¶ 53 (*quoting* Adolor Corp., Prospectus Supp., S-3 (Oct. 29, 2003)).)

4. Study 308

Study 308 enrolled patients from February 2002 to November 2003 and included patients undergoing bowel resections and simple and radical hysterectomies. (Am. Compl. ¶ 55.) On January 13, 2004, Adolor announced the results of Study 308. (*Id.*) The study failed at both the 6 mg and 12 mg dosage levels. Consequently, Adolor's stock price deceased by 37%, closing at $13.73 per share on a volume of 12.7 million shares. (*Id.*) During a conference call that day, Defendant Peacock indicated that the results had not been analyzed by subgroups, stating:

> [J]ust to clarify that, [the analysis] is a prospectively defined subgroup analysis, it's not a prospectively defined subgroup for purposes of primary analysis. But it's not as though we went and post[ed] the data, and said, let's call that a subgroup. Our SAP, we say up front, that's a subgroup we're going to look at. But again, I also want to be clear to say that it was not a predefined subgroup for purposes of primary analysis. But it is a predefined subgroup.

(*Id.* ¶ 56.)

C. Aftermath of Study 302, Study 308, and Study 313

On February 24, 2004, Adolor issued a press release titled, "Adolor's Entereg (alvimopan) Receives FDA Fast Track Designation for Management of Postoperative Ileus." This release stated in pertinent part:

> Adolor Corporation announced today that the United States Food and Drug Administration (FDA) has designated Entereg (alvimopan) as a Fast Track product for the management of postoperative ileus. (POI). The FDA's notification of Fast Track designation indicated that postoperative ileus is a serious condition for which no drugs have been approved.
>
> The Fast Track Programs of the FDA are designed to faciliate the development and expedite the review of new drugs that are intended to treat serious or life-threatening conditions and that demonstrate the potential to address unmet medical needs.
>
> "Adolor and our collaborator for Entereg, GlaxoSmithKline, are dedicated to advancing the development of Entereg for the management of postoperative ileus and we are pleased that the FDA has granted Entereg Fast Track designation," said Bruce A. Peacock, president and chief executive officer of Adolor corporation. "We are working diligently to submit an NDA for Entereg late in the first half of 2004."

(*Id.* ¶ 59.)

In May 2004, Variant Research Corporation ("Variant"), a private investment firm, reviewed the data from Adolor's Phase III studies and concluded that Adolor used inconsistent approaches in declaring some of the results statistically significant. (*Id.* ¶ 62.) According to Variant, Adolor's inclusion of simple hysterectomy patients in Study 302 and Study 308 led to mixed results because these patients have considerably shorter hospital stays than the others, leading to questions of whether Entereg had any effect on them at all. (*Id.* ¶ 64.) Based on its conclusions, Variant rated Adolor's stock as a "sell/sell short" stock with a target price of $10.00. (*Id.* ¶ 66.) In July 2004, Lehman Brothers issued a report cautioning investors about Entereg after the Phase III trials were complete. (*Id.* ¶ 67.) In its report, Lehman cut Adolor's stock valuation in half from $26.00 to $13.00, due in part to concerns regarding potential "data

volatility" that might result from differences between the test centers that conducted Study 313 and the test centers in Europe used by Glaxo to conduct a similar study. (*Id.*) The report stated:

> While the previous success of Entereg in study #313 and a similarly designed European study provides reasonable likelihood of success we believe that there remains a certain degree of data risk from this trial. In particular, given the importance of center selection, advanced training of study nurses and the variability and subjective nature of patient progress tracking we believe that the lack of prior experience of centers with POI trials creates some data risk in the European study. Indeed, [Adolor] itself has acknowledged early on that there is a great variability between centers that creates data volatility and had credited part of the success of study #313 to having the right centers. To the extent that it is difficult to say whether "right" centers have been enrolled by [Glaxo] in Europe it is therefore difficult to ascertain the degree of risk to this trial. We would also highlight the potential for different and potentially highly variable peri- and post-operative care in Europe that may introduce additional risk to the trial design. Indeed, given that cost-constrained socialized medical systems may tend to discharge patients out of hospital sooner there may be the same potential for problem as that seen in the hysterectomy patients where patients are not in hospital long enough to manifest a benefit.

(*Id.* (emphasis omitted).) In light of these findings, Lehman recommended that investors "stay on the sidelines" pending the FDA's review of Entereg. (*Id.*)

On December 23, 2004, Adolor released the results of Glaxo's European Phase III clinical trial of Entereg, consisting of bowel resection patients. (*Id.* ¶ 70.) No simple hysterectomy patients were included in Glaxo's study. (*Id.*) This trial failed at both the 6 mg and 12 mg dosage levels. That same day, Adolor's stock fell almost 46% to $8.78 per share on volume of nearly 19 million shares. (*Id.* ¶ 71.) On January 10, 2005, Adolor issued a statement indicating that the FDA asked them to submit the results from the Glaxo study as part of its review of the Entereg NDA. (*Id.* ¶ 72.)

D. Statements at Issue

The Amended Complaint alleges a series of false or misleading statements by Defendants

with respect to the development of Entereg. Plaintiffs allege essentially five factual misrepresentations, several of which occurred in more than one statement or were made by more than one Defendant. The substance of each purported misrepresentation and Plaintiffs' argument addressing why the statement is misleading follows:

(1) Public statements made on April 2, 2003, in a press release and during a conference call in which Adolor told investors that Study 302's top-line results were statistically significant at the 6 mg dosage level, but not at 12 mg. (*Id.* ¶¶ 37-38 (*quoting* Adolor Corp., Current Report (Form 8-K), Ex. 99.1 (Apr. 2, 2003)).) Plaintiffs contend that this information was misleading because Defendants knew, but failed to disclose, that Entereg's failure at the 12 mg dosage level was "directly related to the lack of a benefit for the drug when used in certain patient subgroups, particularly simple hysterectomy patients." (*Id.* ¶ 39.)

(2) Defendant Bruce Wallin's statement during the April 2, 2003 conference call concerning Study 302 that indicated that the Phase III trial was a "randomized, multi-center study enrolling approximately 450 patients across three groups." (*Id.* ¶ 37.) Plaintiffs contend that this statement was false or misleading because Adolor failed to properly "randomize" Study 302 because the different patient subgroups were not distributed across varying study sites, but consisted of one patient type at each study center. (*Id.* ¶¶ 40(a)-(f).) This in turn allowed Defendant's to learn which patients benefitted most from Entereg. (*Id.* ¶¶ 40(d), (f).) Plaintiffs further contend that Study 302 was not "double-blinded" because Adolor's scientists received "unblinded data packets" from each study center, allowing them to form opinions about Study 302 before the study was complete. (*Id.* ¶ 40(b).)

(3) Public statements that Entereg achieved statistically significant results at both the 6 mg and 12 mg dosage levels in Study 313. (*Id.* ¶ 42 (*quoting* Adolor Corp., Current Report (Form 8-K), Ex. 99.1 (Sept. 23, 2003)); *see also id.* ¶¶ 43-47.) Included in this theory of misrepresentation are statements made by Defendants during the conference call with analysts discussing the results of Study 313 (*id.* ¶ 50) and public statements regarding Adolor's stock offering in November 2003, including the prospectus and a press release dated November 5, 2003. (*Id.* ¶ 52 (*quoting* Adolor Corp., Current Report (Form 8-K), Ex. 99.1 (Nov. 11, 2003)).) Plaintiffs claim that Defendants' public statements regarding the results of Study 313 and their relationship to the results of Study 302 were misleading for the following reasons:

(a) Study 313 was "rigged": Defendants improperly used information obtained in Study 302 to manipulate the results of Study 313 (*id.* ¶¶ 40(f), 50(c));

(b) the reported declaration of statistical significance in Study 313 was faulty and inconsistent (*id.* ¶¶ 50(d); *see also id.* ¶ 43);

(c) Defendants failed to disclose Entereg's impact on various subgroups despite having knowledge of discrepancies in patient subgroups as is evidenced by the fact that Defendants held extensive meetings to discuss this issue (*id.* ¶ 49); and

(d) Defendants failed to concede that the success of Study 313 was based in large part on the lack of simple hysterectomy patients and differences in the selection of study centers (*id.* ¶ 50(a)).

(4) Public statements concerning Study 308. Plaintiffs allege that Defendants knew, but failed to disclose, that the poor results of Study 308 resulted from the inclusion of simple hysterectomy patients, and that Glaxo's European study, which was similar to the patient enrollment in Study 313, was at great risk of failure because it was not rigged like Study 313. (*Id.* ¶¶ 50(b), 55-58.)

(5) Defendants' press release announcing that Entereg was designated as a "Fast-Track" product. (*Id.* ¶ 59.) Plaintiffs allege that the press release was misleading because it was unreasonable to expect that the FDA would approve the drug for marketing on the basis of the mixed results obtained in the three studies. (*Id.* ¶¶ 59-60.)

II. LEGAL STANDARD

Federal Rule of Civil Procedure 12(b)(6) permits courts to dismiss complaints for "failure to state a claim upon which can be granted." Fed. R. Civ. P. 12(b)(6). When considering a Rule 12(b)(6) motion to dismiss, courts must accept all well-pleaded allegations in complaints as true. *In re Adams Golf, Inc. Sec. Litig.*, 381 F.3d 267, 273 (3d Cir. 2004). To withstand a motion to dismiss, the allegations in the complaint must be "enough to raise a right to relief above the speculative level, on the assumption that all the allegations in the complaint are true, (even if doubtful in fact)." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007) (internal citations

omitted). Complaints alleging securities fraud under the Exchange Act must satisfy the heightened pleading requirements imposed by the Private Securities Litigation Reform Act ("PSLRA"), 15 U.S.C. § 78u-4, and Federal Rule of Civil Procedure 9(b). *See GSC Partners CDO Fund v. Washington*, 368 F.3d 228, 237-38 (3d Cir. 2004).

Congress enacted the PSLRA "to remedy the tactic of filing securities complaints to force unwarranted settlements." *In re PMA Capital Corp. Sec. Litig.*, No. 03-6121, 2005 WL 1806503, at *5 (E.D. Pa. July 25, 2005). In *In re Advanta*, the Third Circuit observed:

> The purpose of the PSLRA was to restrict abuses in securities fraud class action suits, including the following: (1) the practice of filing lawsuits against issuers of securities in response to any significant change in stock price, regardless of defendants' culpability; (2) the targeting of "deep pocket" defendants; (3) the abuse of the discovery process to coerce settlement; and (4) manipulation of clients by class action attorneys.

In re Advanta Sec. Litig., 180 F.3d 525, 531 (3d Cir. 1999). A complaint alleging securities fraud must "specify each statement alleged to have been misleading, the reasons or the reasons why the statement is misleading, and, if an allegation regarding the statement or omission is made on information and belief, the complaint shall state with particularity all facts on which that belief is formed." 15 U.S.C. § 78u-4(b)(1)(B). Moreover, the complaint must, "with respect to each act or omission alleged to violate [the Exchange Act], state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind." *Id.* § 78u-4(b)(2); *see generally Tellabs v. Makor Issues & Rights, LTD.*, 127 S. Ct. 2499 (2007) (discussing pleading requirements for securities fraud claims). In this regard, "the PSLRA alters the normal operation of inferences under [Rule] 12(b)(6)," which requires that all reasonable inferences be construed in a light most favorable to plaintiffs. *In re Digital Island Sec. Litig.*,

357 F.3d 322, 329 (3d Cir. 2004); *In re Rockefeller Ctr. Props., Inc. Sec. Litig.*, 311 F.3d 198, 224 (3d Cir. 2002) ("[U]nless plaintiffs in a securities fraud action allege facts . . . with the requisite particularity . . . they may not benefit from inferences flowing from vague or unspecific allegations – inferences that may arguably have been justified under a traditional Rule 12(b)(6) analysis."), *overruled on other grounds by Phillips v. County of Allegheny*, 515 F.3d 224, 231 (3d Cir. 2008); *Greebel v. FTP Software, Inc.*, 194 F.3d 185, 196 (1st Cir. 1999) ("The most salient feature of the PSLRA is that whatever the characteristic pattern of the facts alleged, those facts must now present a strong inference of scienter. A mere reasonable inference is insufficient to survive a motion to dismiss."); *see also Morse v. Lower Merion Sch. Dist.*, 132 F.3d 902, 906 (3d Cir. 1997) (relying on general principle that reasonable inferences must be "view[ed] in a light most favorable to the plaintiff" when considering a motion to dismiss); *Phillips*, 515 F.3d at 231(stating that *Twombly*, 550 U.S. 544, did not undermine principle of drawing all reasonable inferences in favor of plaintiffs when considering a motion to dismiss).

Plaintiffs must also comply with the heightened pleading requirements for fraud set out in the Federal Rules of Civil Procedure. Rule 9(b) requires that "[i]n all averments of fraud or mistake, the circumstances constituting fraud or mistake shall be stated with particularity." Fed. R. Civ. P. 9(b). To satisfy this requirement, a plaintiff must plead "(1) a specific false representation [or omission] of material fact; (2) knowledge by the person who made it of its falsity; (3) ignorance of its falsity by the person to whom it was made; (4) the intention that it should be acted upon; and (5) that the plaintiff acted upon it to his damage." *In re Suprema Specialties, Inc. Sec. Litig.*, 438 F.3d 256, 276 (3d Cir. 2006) (*citing In re Rockefeller*, 311 F.3d

at 216).[9] The Third Circuit has held that, in order to satisfy these elements, a complaint must allege "all of the essential factual background that would accompany the first paragraph of any newspaper story – that is, the 'who, what, when, where and how' of the events at issue." *In re Rockefeller*, 311 F.3d at 217 (*quoting In re Burlington Coat Factory Sec. Litig.*, 114 F.3d 1410, 1422 (3d Cir. 1997)).

III. LEGAL ANALYSIS

A. 10b-5 Claims

"To state a claim for relief under section 10(b), a plaintiff must plead facts demonstrating that (1) the defendant made a materially false or misleading statement or omitted to state a material fact necessary to make a statement not misleading; (2) the defendant acted with scienter; and (3) the plaintiff's reliance on the defendant's misstatement caused him or her injury." *CALPERS v. Chubb Corp.*, 394 F.3d 126, 143 (3d Cir. 2004); *see also In re Ikon Office Solutions, Inc.*, 277 F.3d 658, 666 (3d Cir. 2002) (*citing GFL Advantage Fund, Ltd., v. Colkitt*, 272 F.3d 189, 212 (3d Cir. 2001), *cert. denied*, 536 U.S. 923 (2002); *Weiner v. Quaker Oats Co.*, 129 F.3d 310, 315 (3d Cir. 1997)).[10]

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[9] "To the extent that Rule 9(b)'s allowance of general pleading with respect to mental state conflicts with the PSLRA's requirement that plaintiff's state with particularity facts giving rise to a strong inference that the defendant acted with scienter, the PSLRA supersedes Rule 9(b) as it relates to Rule 10b-5 actions." *In re Advanta*, 180 F.3d at 531 n.5.

[10] Rule 10b-5 makes it unlawful for any person:

> (a) To employ any device, scheme, or artifice to defraud, (b) [t]o make any untrue statement of a material fact or to omit to state a material fact necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading, or (c) [t]o engage in any act, practice or course of business which operates or would operate as a fraud or deceit upon any person, in connection with the purchase or sale of any security.

1. Materially False or Misleading Statements

Addressing first the question of whether the statements made by Defendants were materially false or misleading, a statement is false or misleading if

> it is factually inaccurate, or additional information is required to clarify it. Misrepresentative statements of fact clearly satisfy this requirement. In addition, misleading statements of subjective analysis or extrapolation, such as opinions, motives or intentions, or forward looking statements, such as projections, estimates and forecasts may be actionable if the speaker does not genuinely and reasonably believe them when made. An omission can also satisfy this element where silence would make other statements misleading or false.

Wallace v. Sys. & Computer Tech. Corp., No. 95-6303, 1997 WL 602808, at *9 (E.D. Pa. Sept. 23, 1997). However, "silence, absent a duty to disclose, is not misleading under Rule 10b-5." *Oran v. Stafford*, 226 F.3d 275, 285 (3d Cir. 2000) (Alito, J.) (*citing Basic Inc. v. Levinson*, 485 U.S. 224, 239 n.17 (1988)).

As discussed above, Plaintiffs identify five categories of representations by Defendants that they assert are materially false or misleading. Of the five, Plaintiffs appear to claim that two categories involved affirmatively false representations: (1) Defendants' assertion that the studies were "randomized" and "double-blinded" (*see* Am. Compl. ¶¶ 37, 40(a)-(f)), and (2) Defendants' statements regarding Study 313, which Plaintiffs claim was "rigged" (*see id.* ¶ 50(c)). The remaining three categories of representations that Plaintiffs identify as materially misleading appear to be premised on omissions of material facts necessary to make the representations not misleading.

Plaintiffs allege that Defendants' comments about the studies being randomized and

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17 C.F.R. § 240.10b-5.

double-blinded were affirmatively false. (*See id.* ¶ 37 (quoting Defendant Bruce Wallin's comment during April 2, 2003 conference call that Study 302 was a "randomized, multi-center study")); *see also* Adolor Corp., Annual Statement (Form 10-K), at 2-3, 13 (Mar. 4, 2004) (noting that all four studies were randomized and double-blinded). Plaintiffs offer definitions of "randomization" and "double blind" in the Amended Complaint. According to Plaintiffs,

> randomization is a method based on chance by which study participants are assigned to a treatment group. . . . A truly randomized study involving patients with particular characteristics would thus distribute these different types of patients among various study sites. Lack of randomization by patient type is material since it would provide an opportunity to learn of bias from site to site for specific patient types.

(Am. Compl. ¶ 40(a).) A "double-blinded" study is one in which

> the patients and the clinical staff do not know which treatment each patient is receiving. Blinding a study prevents personal bias from influencing their reactions and the study results. An improper or broken blind would permit clinical staff to learn and form opinions about the study results before the end of the trial.

(*Id.* ¶ 40(b).) Plaintiffs do not support their definitions with citations to FDA guidelines or assert that the definitions are the industry standard. These definitions are little more than conclusory allegations that we need not consider.

This view of Plaintiffs' definition of "randomization" is bolstered by an FDA-published Guidance for Industry regarding clinical trials, which defines randomization as "a process of assigning trial subjects to treatment or control groups using an element of chance to determine the assignments in order to reduce bias." Ctr. for Biologics Evaluation & Research, U.S. Dep't of Health & Human Servs., *Guidance for Industry, E6 Good Clinical Practices: Consolidated Guidance* 7 (1996) *available at* http://www.fda.gov/cder/guidance/959fnl.pdf. Even if we consider Plaintiffs' definition of randomization in conjunction with the definition in the FDA's

Guidance for Industry, the most favorable inference that can be drawn in Plaintiffs' favor is that there are grounds for disagreement about how to conduct a randomized study when that study includes multiple sites. This does not support an inference that Defendants' statements were false or misleading when made.[11] Indeed, the FDA does not appear to have taken exception to how the Entereg Phase III trials were randomized when reviewing the study results in the NDA.

The same is also true with regard to Plaintiffs' contention that the study was not properly "double-blinded" because the data packets were marked by study site number, principal investigator, and site coordinator. (*See* Am. Compl. ¶¶ 40(b), (e).) In another Guidance for

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[11] In the Amended Complaint, Plaintiffs rely on another FDA Guidance for Industry to support their argument that the Phase III trials should have been randomized across study centers:

> The primary variable(s) is often systematically related to other influences apart from treatment. For example, there may be relationships to covariates such as age and sex, or there may be differences between specific subgroups of subjects, such as those treated at the different centers of a multicenter trial. In some instances, an adjustment for the influence of covariates or for subgroup effects is an integral part of the planned analysis and hence should be set out in the protocol. Pretrial deliberations should identify those covariates and factors expected to have an important influence on the primary variable(s), and should consider how to account for these in the analysis to improve precision and to compensate for any lack of balance between treatment groups. If one or more factors are used to stratify the design, it is appropriate to account for those factors in the analysis. When the potential value of an adjustment is in doubt, it is often advisable to nominate the unadjusted analysis as the one for primary attention, the adjusted analysis being supportive. Special attention should be paid to center effects and to the role of baseline measurements of the primary variable. It is not advisable to adjust the main analyses for covariates measured after randomization because they may be affected by the treatments.

(Am. Compl. ¶ 31 (*quoting* Ctr. for Biologics Evaluation & Research, U.S. Dep't of Health & Human Servs., *Guidance for Industry, E9 Statistical Principles for Clinical Trials* 33 (1998) *available at* http://www.fda.gov/cder/guidance/ICH_E9-fnl.pdf).) Again, this may support an argument that the Entereg Phase III trials could have been designed better. It does not support a finding of fraud.

Industry, the FDA defines "double-blind" to mean that "both subjects and investigators, as well as sponsor or investigator staff involved in the treatment or clinical evaluation of subjects, are unaware of each subject's assigned treatment." *See* Ctr. for Biologics Evaluation & Research, U.S. Dep't of Health & Human Servs., *Guidance for Industry, E10 Choice of Control Group and Related Issues in Clinical Trials* 4 (2001) *available at* http://www.fda.gov/cder/guidance/4155fnl.pdf. Plaintiffs do not allege that the data packets revealed the assigned treatment in violation of the FDA's standards. Without allegations that Defendants' use of the term directly contradicted either the FDA's definition or common industry usage, Defendants' statements regarding the double-blinded nature of the Phase III Entereg trials could not have been false or misleading when made. Again, based on the record before us, the FDA does not appear to have disapproved of the methods and procedures employed in the Entereg Phase III trials, and it is the FDA that is in the best position to monitor compliance with its regulations.[12] In any event, we find nothing in the allegations, law, or guidelines now before us that indicates that data packets must be completely unmarked.

While it may be desirable to eliminate biases to the maximum extent possible, "[w]here a company accurately reports the results of a scientific study, it is under no obligation to second-guess the methodology of that study. Medical researchers may well differ with respect to what constitutes acceptable testing procedures, as well as how best to interpret data garnered under various protocols." *Padnes v. Scios Nova Inc.*, No. 95-1693, 1996 WL 539711, at *5 n.1 (N.D.

[12] We note that the FDA approved Entereg on May 20, 2008, to treat POI in patients undergoing bowel resection surgery. *See* Adolor Corp., Current Report (Form 8-K), Ex. 99.1 (May 21, 2008) (announcing FDA approval of Entereg).

Cal. Sept. 18, 1996). Plaintiffs' allegations in the Amended Complaint regarding Defendants' statements that the Phase III trials were randomized and double-blinded amount to disagreements over the proper methodology and conduct of clinical studies.[13] These allegations are not sufficient to establish falsity for purposes of a Rule 10b-5 claim.

Plaintiffs' second theory of affirmative fraud alleges that Defendants used the information learned about certain test center biases from Study 302 to manipulate the results of Study 313. (*See* Am. Compl. ¶¶ 40(f), 50(c).) However, the Amended Complaint does not allege facts detailing exactly how Defendants rigged Study 313 to guarantee a successful outcome. Specifically, Plaintiffs' allegations lack the "'who, what, when, where and how' of the events at issue," namely the scheme to rig Study 313's results, required to satisfy Rule 9(b). *In re Rockefeller*, 311 F.3d at 217 (citation omitted). Plaintiffs' allegations regarding the "rigging" of Study 313 lack specificity. For example, Plaintiffs rely on information provided by a confidential witness[14] to allege the existence of so-called "bad centers," which Defendants excluded from Study 313. (*See* Am. Compl. ¶ 50(c).) However, the information that the confidential witness provides only suggests that there may have been centers where principal investigators deviated from protocol. It does not provide the basis for a well-founded allegation that Defendants used or manipulated this to their advantage.

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[13] This analysis overlaps with our analysis concerning whether Defendants' had a duty to disclose information. As the court in *Padnes* observed, "[t]he securities laws do not . . . require that companies who report information from imperfect studies include exhaustive disclosures of procedures used, . . . [or] various opinions with respect to the effects of these choices on the interpretation of the outcome data." 1996 WL 539711, at *5.

[14] Plaintiffs rely on the testimony of three confidential witnesses to support the allegations in the Amended Complaint. We discuss the information provided by these witness in greater detail in our analysis of scienter.

Moreover, there is an apparent explanation for the discrepancies between Study 302 and Study 313: Study 302 included simple hysterectomy patients and Study 313 did not. Defendants made it clear from the outset of the Phase III trial that Study 302 and Study 308 would include simple hysterectomy patients and that these patients would be excluded from Study 313. (*See, e.g.*, Doc. No. 42, Ex. 10, Adolor Conference Call Tr. of Sept. 23, 2003, at 4 ("[Study 313] included male and female patients . . . undergoing a bowel resection or a radical abdominal hysterectomy. As compared to Study 302 . . . , [Study 313] did not enroll simple hysterectomy patients which . . . were included in . . . Study 302 . . . ."); Am. Compl. ¶ 53 (*quoting* Adolor Corp., Prospectus Supplement, S-3 (Oct. 29, 2003), which states that Study 302 included simple hysterectomy patients and Study 313 excluded simple hysterectomy patients).) It follows that the exclusion of simple hysterectomy patients from Study 313 does not, by itself, support Plaintiffs' theory that Defendants rigged the study. Nor is the fact that the results of Study 313 were slightly better than those of Study 302 evidence of wrongdoing.

Plaintiffs allege that the results of Study 313 were "remarkably" better than those of Study 302 because of Defendants' fraud. Based on the allegations in the Amended Complaint and Defendants' public statements, this does not appear to be the case. Study 302 achieved statistical significance at one dosage level and Study 313 achieved statistical significance at both, with the likely difference being that the former included simple hysterectomy patients and the latter did not.[15] Finally, Plaintiffs provide no explanation as to why Defendants would have

[15] Plaintiffs' reliance on the review of Entereg data conducted by Variant does not alter our analysis. (*See* Am. Compl. ¶¶ 62-66.) Variant's statistician identified what he believed were problems with Adolor's statistical analysis of the Phase III trials that led to what Plaintiffs describe as "inconsistent approaches in declaring statistically significant results for the primary

rigged Study 313, but not Study 308. In the absence of pleading that sets out the plan in detail or a compelling motive, and in the presence of a plausible explanation, Plaintiffs' study-rigging theory fails.

The gravamen of Plaintiffs' remaining theories of misrepresentation is that Defendants made public statements about the top-line results of the Phase III studies; that Defendants had knowledge of the performance of Entereg in patient subgroups – specifically, simple hysterectomy patients – that were material to the statistical significance of the top-line results and, as a result, the likelihood of a successful NDA and eventual FDA approval for Entereg; and that Defendants did not disclose this information.[16] These allegations of securities fraud revolve primarily around Defendants' alleged omissions to public statements regarding or relying on the results of Study 302. Plaintiffs allege that Defendants concealed the fact that Entereg's failure at the 12 mg level in Study 302 was directly related to its ineffectiveness in simple hysterectomy patients. According to Plaintiffs, Defendants omitted this material fact from any of their Phase III public disclosures and used that omission to create a false sense of optimism regarding the results of both Study 313 and Study 308.

It is well-settled that even material omissions cannot form the basis for a securities fraud

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endpoint in the three studies." (*Id.* ¶ 63.) The fact that Variant's statistician reached a different conclusion than Adolor does not establish that Adolor's interpretation of the results were false or misleading. As with the discussion of Adolor's use of the terms randomized and double-blinded, the conclusions offered by Variant (and the inferences drawn from those conclusions by Plaintiffs) establish that there may be a disagreement about how to conduct and analyze a study. It does not suggest that Adolor's approach was wrong or improper, and therefore misleading. Our analysis of scienter *infra* supports this conclusion.

[16] This includes Plaintiffs' allegations regarding the February 24, 2004 press release announcing that the FDA gave Entereg a Fast Track designation. (Am. Compl. ¶ 59.)

claim absent a duty to disclose that information. *Oran*, 226 F.3d at 285 ("Even non-disclosure of material information, *e.g.*, deaths connected to a drug, will not give rise to liability under Rule 10b-5 unless the defendant had an affirmative duty to disclose that information."); *see also Basic*, 485 U.S. at 239 n.17 ("Silence, absent a duty to disclose, is not misleading under Rule 10b-5."). "[A] duty to disclose may arise only when there is an incident of insider trading, or presence of a statute requiring disclosure, or there was an inaccurate, incomplete or misleading prior disclosure requiring a corrective statement." *In re Intelligroup Sec. Litig.*, 527 F. Supp. 2d 262, 282 (D.N.J. 2007) (citations and alterations omitted). Plaintiffs do not allege that Defendants engaged in prohibited insider trading; nor do they allege that a statute required disclosure of the subgroup data. That leaves allegations of inaccurate, incomplete, and misleading prior disclosures as the sole basis on which Plaintiffs may pursue a claim based on a duty-to-disclose theory.

Plaintiffs do not allege facts sufficient to establish any inaccuracy, incompleteness, or misrepresentation. While we are sensitive to the fact that general public has a right to rely on a company's public statements about its products before investing, Defendants never gave Entereg their unconditional stamp of approval. *See In re Discovery Lab. Sec. Litig. I*, No. 06-1820, 2006 WL 3227767, at *12 n.25 (E.D. Pa. Nov. 1, 2006) ("If [Defendant] had announced 'we are certain that we have conducted sufficient clinical trials to obtain EMEA approval,' this case might be different. [Defendant] made no such flat-footed statement."). Nor did they announce how the different patient subgroups responded to Entereg or do anything to create an impression that the results were consistent across the subgroups. Defendants consistently stated that they would only discuss the top-line results of each study, and refused to comment on subgroups until all three studies were complete per their agreement with Glaxo. (*See, e.g.*, Am. Compl. ¶ 44;

Doc. No. 42, Ex. 11, Adolor Conference Call Tr. of Apr. 2, 2003, at 20 ("Our agreement right up front with our partner [Glaxo] was that we would talk about the combined top-line results and that's all we can speak to today.").) *Cf. Noble Asset Mgmt. v. Allos Therapeutics, Inc.*, No. 04-1030, 2005 WL 4161977, at *7 (D. Colo. Oct. 20, 2005) (finding that the defendants made no false or misleading statements concerning subgroups because, *inter alia*, "subgroup analyses are considered exploratory in 'most cases' and ordinarily will not provide a basis for definitive conclusions"). Defendants repeatedly warned investors not to draw any final conclusions about Entereg's overall success until all three studies were complete and the full data set could be analyzed. *See, e.g.*, Adolor Corp., Annual Report (Form 10-K), at 38 (March 18, 2003) ("We may suffer significant setbacks in advanced clinical trials, even after promising results."); Adolor Corp., Quarterly Report (Form 10-Q), at 12 (May 14, 2003) ("We do not know whether our existing or any future trials will demonstrate sufficient safety and efficacy necessary to obtain the requisite regulatory approvals or will result in marketable products."). Regardless of whether information about the efficacy of Entereg in patient subgroups was material, Defendants were under no obligation to disclose it.[17] As a result, Plaintiffs cannot state a Rule 10b-5 claim.

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[17] It is not enough to allege that the Company "'[a]t one time . . . bathe[d] itself in favorable light' but 'later disclose[d] that things [were] less rosy.'" *See In re Advanta*, 180 F.3d at 538 (*quoting DiLeo v. Ernst & Young*, 901 F.2d 624, 627 (7th Cir. 1990)). Investors were aware that the patient sample in Study 313 differed from that of Study 302, making any conclusions about the ultimate success of the Phase III trial premature. Indeed, analysts covering Adolor stock repeatedly asked about breakdowns of the Phase III trials by subgroup. For example, during the September 23, 2003, conference call, analyst Jim Birchenoff of Lehman Brothers asked Defendant Peacock: "do you have any concerns about the confounding impact of simple hysterectomies in any other trial?" (Am. Compl. ¶ 47.) Defendant Peacock replied: "we haven't spoken about the information from study 302, broken out by the patient types." (*Id.*; *see also id.* ¶ 44 (noting that Defendant Peacock "told the investment community that the defendants weren't prepared to discuss more than the 'top-line results'").) Thus, the investment community

Finally, we note that investing in a start-up pharmaceutical company like Adolor involves a certain amount of risk on the part of investors. No matter how safe that risk may seem at the time, there are no guarantees, and Defendants never suggested otherwise. *See In re Discovery Lab. Sec. Litig. II*, No. 06-1820, 2007 WL 789432, at *3 (E.D. Pa. Mar. 15, 2007) ("A reasonable investor in an early stage pharmaceutical company should be aware that the FDA may prevent a company from marketing a drug for a wide variety of regulatory failures."). The fact that Plaintiffs now suffer from buyer's remorse does not entitle them to relief under Rule 10b-5. *See Arazie v. Mullane*, 2 F.3d 1456, 1458 (7th Cir. 1993) ("'Because only a fraction of financial deteriorations reflect [] fraud,' . . . plaintiffs in securities cases must provide enough information about the underlying facts to distinguish their claims from those of disgruntled investors." (*quoting DiLeo v. Ernst & Young*, 901 F.2d 624, 627 (7th Cir. 1990))); *see also Zucker v. Quasha*, 891 F. Supp. 1010, 1017 (D.N.J. 1995) (holding that an "omission that is misleading only in hindsight" cannot form basis of securities claim), *aff'd*, 82 F.3d 408 (3d Cir. 1996); *see also In re Advanta*, 180 F.3d at 538 ("[V]ague and general statements of optimism 'constitute no more than 'puffery' and are understood by reasonable investors as such." (*quoting In re*

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was aware that the results discussed by Defendants were limited to top-line results.

It was also clear that the subgroup data that was initially unavailable would eventually become public. (*See, e.g.*, Am. Compl. ¶ 56 (quoting January 13, 2004, conference call in which Defendant Jackson indicated to a Merrill Lynch analyst that the data from Study 308 would be available in approximately 21 months from the time the top-line results were released).) Investors had knowledge that there were patient subgroups for which data was unavailable and that a potential for discrepancies in efficacy across the subgroups existed. In other words, they knew there were significant risks to purchasing Adolor stock before all the data regarding the studies was released. Moreover, as noted above, Plaintiffs cite to no statements and allege no facts that suggest that Defendants took any affirmative steps to create an appearance that the study results were consistent across subgroups. To the contrary, Defendants frequently reminded investors that the top-line results were not broken down by subgroup.

Burlington, 114 F.3d at 1428 n.14)).

As the foregoing analysis makes clear, the Amended Complaint fails to state a Rule 10b-5 because Plaintiffs have not alleged facts sufficient to show that the statements at issue were false or misleading. That alone is enough to warrant dismissing the Amended Complaint. However, Plaintiffs' Rule 10b-5 theory suffers from an even more apparent defect. The facts alleged do not establish the strong inference of scienter required by the PSLRA.

2. Scienter

"To establish liability under § 10(b) and Rule 10b-5, a private plaintiff must prove that the defendant acted with scienter, 'a mental state embracing intent to deceive, manipulate, or defraud.'" *Tellabs*, 127 S. Ct. at 2507 (*quoting Ernst & Ernst v. Hochfelder*, 425 U.S. 185, 193-94 (1976)).[18] A complaint alleging securities fraud must allege facts that create a "strong inference" of scienter. 15 U.S.C. § 78u-4(b)(2). A "strong inference" is one that is "more than merely plausible or reasonable–it must be cogent and at least as compelling as any opposing inference of nonfraudulent intent." *Tellabs*, 127 S. Ct. at 2504.

In determining whether a securities fraud complaint adequately pleads scienter, a reviewing court "must consider the complaint in its entirety, as well as other sources courts ordinarily examine when ruling on 12(b)(6) motions to dismiss, in particular documents incorporated into the complaint by reference and matters of which a court may take judicial

[18] The Third Circuit has defined "scienter" as "a mental state embracing intent to deceive, manipulate or defraud, or, at a minimum, highly unreasonable (conduct), involving not merely simple, or even excusable negligence, but an extreme departure from the standards of ordinary care, . . . which presents a danger of misleading buyers or sellers that is either known to the defendant or is so obvious that the actor must have been aware of it." *In re Alpharma*, 372 F.3d at 148 (*citing In re Ikon*, 277 F.3d at 667); *see also Hochfelder*, 425 U.S. at 193 n.12.

notice." *Id.* at 2509. Thus, the inquiry is whether "all of the facts alleged, taken collectively, give rise to a strong inference of scienter, not whether any individual allegation, scrutinized in isolation, meets that standard." *Id.* Finally, when determining whether a plaintiff's allegations give rise to a "strong" inference of scienter, "the court must take into account plausible opposing inferences." *Id.* In *Tellabs*, the United States Supreme Court stated that "the strength of an inference cannot be decided in a vacuum," adding that:

> [T]he inquiry is inherently comparative: How likely is it that one conclusion, as compared to others, follows from the underlying facts? To determine whether the plaintiff has alleged facts that give rise to the requisite "strong inference" of scienter, a court must consider plausible nonculpable explanations for the defendant's conduct, as well as inferences favoring the plaintiff. The inference that the defendant acted with scienter need not be irrefutable, *i.e.*, of the "smoking-gun" genre, or even the "most plausible of competing inferences." . . . Yet the inference of scienter must be more than merely "reasonable" or "permissible" – it must be cogent and compelling, thus strong in light of other explanations. A complaint will survive . . . only if a reasonable person would deem the inference of scienter cogent and at least as compelling as any opposing inference one could draw from the facts alleged.

Id. at 2510 (internal citations omitted).

Plaintiffs' theory of fraud provides no basis for finding a strong inference that Defendants acted with scienter. The principal fault in their theory is that it does not account for the failure of Study 308 to establish statistical significance at either the 6 mg or 12 mg dosage levels. If Plaintiffs were withholding information regarding Study 302 and rigging Study 313 in a scheme to defraud investors, one would expect them to engage in similar fraudulent conduct with regard to Study 308. The three studies were all part of the same Phase III trials process, the results of which were subject to review by the FDA and scrutiny from investors. It is difficult to infer a mental state embracing intent to deceive, manipulate, or defraud where Defendants' conduct is inconsistent in this way. Similarly, there are no allegations that suggest that Defendants

commenced a course of fraudulent conduct with Study 302 and Study 313 only to abandon the conduct with regard to Study 308. Put simply, Plaintiffs' theory does not make sense on the facts alleged, let alone present a cogent or compelling rationale for inferring scienter.

This conclusion is supported by Plaintiffs' failure to articulate a persuasive motive for Defendants to have perpetrated a fraud with regard to Study 302 and Study 313 and not with regard to Study 308. *See In re Digital Island*, 357 F.3d at 331 (agreeing with district court's observation that the "'plaintiffs' theory makes little economic sense because the directors' own stock options would have been devalued if they tried to sell the company for less than full price'") (citation omitted).[19] While the Supreme Court made it clear in *Tellabs* that the "absence of a motive allegation is not fatal" to a Rule 10b-5 claim, the Court also stated that "allegations must be considered collectively; the significance that can be ascribed to an allegation of motive, or lack thereof, depends on the entirety of the complaint." 127 S. Ct. at 2511. Considering the totality of the Amended Complaint, the absence of motive here is significant.

The Amended Complaint makes no allegations that Defendants gained any individual

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[19] *See also Oran*, 226 F.3d at 289 (affirming district court's dismissal of Rule 10b-5 claim against the individual defendant-officers who traded no stock during relevant time period and thus had no fraudulent intent); *In re Discovery Labs. II*, 2007 WL 789432, at *7 (finding allegations of insider trading "inadequate" to satisfy "motive and opportunity" prong where the defendants' stock sales totaled between half and two-thirds, and less than a third, of their total holdings); *In re Freemarkets, Inc. Sec. Litig.*, No. 00-024, 2000 WL 33914766, at *10 n.12 (W.D. Pa. Dec. 26, 2000) (noting that "[i]t is difficult to perceive the motive of individual defendants" absent allegations of insider trading). *Cf. U.S. Bioscience Sec. Litig.*, 806 F. Supp. 1197, 1204-05 (E.D. Pa. 1992) (inferring scienter where Defendants sold nearly $1 million in stock days after issuing false or misleading statements concerning clinical trial results); *In re Neopharm Inc. Sec. Litig.*, No. 02-2976, 2003 WL 262369, at *14 (N.D. Ill. Feb. 7, 2003) (determining that the plaintiffs adequately plead scienter where the defendants cashed in stock based on inside information).

benefit from their alleged fraud. Indeed, Defendants not only held onto their shares of Adolor stock during the Class Period, they actually increased their holdings incrementally throughout the Class Period.[20] Such conduct raises a compelling inference *against* scienter. Certainly, if Defendants had sold their Adolor stock before the value of the stock dropped, Plaintiffs would have a sufficient factual basis to allege scienter. *See In re Suprema*, 438 F.2d at 256 (finding scienter where the defendants' insider sales came shortly after misstatements lead to artificially inflated stock price). This did not happen.

Plaintiffs nevertheless argue that Defendants stood to benefit from Adolor's public stock offering and their Agreement with Glaxo. However, these are not the type of financial benefits that support a finding of scienter. Director and officer decisions that benefit the entire company and offer no individual benefit to the directors are completely consistent with a board's duty to manage the company's affairs and steer it towards profitability. *See In re Advanta*, 180 F.3d at 535 ("Motives that are generally possessed by most corporate directors and officers do not suffice; instead, plaintiffs must assert a concrete and personal benefit to the individual defendants

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[20] Defendants, citing to Adolor's public filings (Form 4s and Schedule 14As), demonstrate that all the Individual Defendants, except Defendant Wallin, had significant net-increases in their share holdings during the class period. (*See* Doc. No. 42 at 13.) We are permitted to take judicial notice of SEC filings in evaluating the allegations in the Amended Complaint. *See In re NAHC, Inc. Sec. Litig.*, 306 F.3d 1315, 1331 (3d Cir. 2002) (finding "no reversible error and completely accept[ing] the district court's" reliance on "documents filed with the SEC, but not relied upon in the Complaint"). We can therefore infer that the Amended Complaint contains no allegations that the Individual Defendants improperly purchased or sold shares because no such purchases or sales occurred. Defendant Wallin, as a non-officer and non-director (*see* Am. Compl. ¶ 14), was not subject to the SEC's reporting requirements, *see* 15 U.S.C. § 78p (establishing disclosure requirements for directors, officers, and principal stockholders); 17 C.F.R. § 249.104 (setting out requirements for Form 4). Thus, we have no information on his trading history. In any event, the Amended Complaint makes no allegations on this point.

resulting from this fraud." (*quoting Kalnit v. Eichler*, 264 F.3d 131, 1239 (2d Cir. 2001))). Even when directors marginally benefit from corporate transactions courts are reluctant to find liability.[21]

Furthermore, the allegations in the Amended Complaint do not make clear that Defendants even knew of the concerns regarding subgroups when they made the representations at issue. Plaintiffs' allegations are insufficient to create an inference that Defendants had knowledge of the problems with simple hysterectomy patients as early as Study 302, let alone purpose or intent to defraud. Plaintiffs claim that Defendants must have learned of this information from their scientists and researchers because of Defendants' positions within the Company. The Third Circuit has concluded that such a generalized inference falls short of the

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[21] *See GSC Partners,* 368 F.3d at 237-38 ("Similar situations arise in every merger; thus, allowing a plaintiff to prove a motive to defraud by simply alleging a corporate defendant's desire to retain his position with its attendant salary, or realize gains on company stock, would force the directors of virtually every company to defend securities fraud actions every time that company effected a merger or acquisition." (*citing Phillips v. LCI Int'l, Inc.*, 190 F.3d 609, 623 (4th Cir. 1999))); *San Leandro Emergency Med. Group Profit Sharing Plan v. Philip Morris Cos.*, 75 F.3d 801, 813-14 (2d Cir. 1996) (finding that a "company's desire to maintain a high bond or credit rating" was insufficient motive for fraud because such motive could be imputed to any company); *Tuchman v. DSC Commc'ns Corp.*, 14 F.3d 1061, 1068 (5th Cir. 1994) ("[I]ncentive compensation can hardly be the basis on which an allegation of fraud is predicated.") (citation omitted); *Herzog v. GT Interactive Software Corp.*, No. 98-0085, 1999 WL 1072500, at *9 (S.D.N.Y. Nov. 29, 1999) (holding that a defendant's "desire to consummate [a] corporate transaction does not constitute a motive for securities fraud"); *Leventhal v. Tow*, 48 F. Supp. 2d 104, 115 (D. Conn. 1999) ("[T]he allegation that the defendants artificially inflated Citizens' stock price in order to 'protect and enhance their executive positions' and 'negotiate as favorable a deal as possible' on a pending employment contract also fail[s] to give rise to a strong inference of scienter. This motive has been rejected routinely."); *Thacker v. Medaphis Corp.*, No. 97-2849, 1998 WL 684595, at *3 (S.D.N.Y. Sept. 30, 1998) (finding the plaintiff's claim that the defendant was motivated by a desire to eliminate competitors and to acquire related companies insufficient to plead scienter because such motive could be imputed to any corporate officer).

PSLRA's heightened pleading standard for state of mind. *See In re Rockefeller*, 311 F.3d at 224 (holding that plaintiffs "may not benefit from inferences flowing from vague or unspecific allegations – inferences that may arguably have been justified under a traditional Rule 12(b)(6) analysis"); *see also In re Possis Med., Inc.*, No. 05-1084, 2007 WL 335051, at *5 (D. Minn. Feb. 1, 2007) ("Absent additional information, it is impossible for plaintiffs to support their contention that this source had advance access to the study's negative results, much less to support their theory that defendants possessed such knowledge.").

Plaintiffs attempt support their claims with information provided by three confidential witnesses (hereinafter, "Confidential Witness One," "Confidential Witness Two," and "Confidential Witness Three"). To the extent that Plaintiffs' allegations purport to establish what Defendants knew based on information gathered from confidential witnesses, those allegations must "satisfy the particularity pleading requirements of Rule 9(b) and the PSLRA by providing 'sufficient documentary evidence and/or a sufficient description of the personal sources of the plaintiff's beliefs.'" *In re Royal Dutch/Shell Transp. Sec. Litig.*, No. 04-374, 2006 U.S. Dist. LEXIS 56778, at *14 (D.N.J. Aug. 14, 2006) (*quoting Chubb*, 394 F.3d at 146-47). Courts in this Circuit apply the following analysis:

> Assessing the particularity of the allegations that rely on confidential sources entails an examination of the detail provided by the confidential sources, the sources' basis of knowledge, the reliability of the sources, the corroborative nature of other facts alleged, including from other sources, the coherence and plausibility of the allegations, and similar indicia. Where a confidential source is not described with sufficient particularity to support the probability that a person in the position occupied by the source would possess the information alleged, such allegations fail to supply the requisite particularity to securities fraud claims.

Id. at 15-16 (*citing Chubb*, 394 F.3d at 147-48) (internal quotations and citations omitted). Thus,

while we "will not . . . disregard averments of fact based on anonymous sources," it has been the practice of courts to require that information provided by confidential witnesses be highly "particularized" and "provide circumstantial assurance that 'a person in the position occupied by the source would possess the information alleged.'" *In re Am. Bus. Fin. Servs., Inc. Sec. Litig.*, 413 F. Supp. 2d 378, 390 (E.D. Pa. 2006) (*quoting In re The Loewen Group Inc. Sec. Litig.*, No. 98-6740, 2003 WL 22436233, at *19 (E.D. Pa. 2003)); *see also Chubb*, 394 F.3d at 147-48 ("Plaintiffs' reliance on confidential sources to supply the requisite particularity for their fraud claims . . . assumes a heightened importance given the inadequacy of their documentary source."). Only then should a court "consider them as part of the constellation of facts alleged for why the defendants' statement is false or misleading.'" *Id.*

Plaintiffs allege that Confidential Witness One is an experienced clinical scientist and former Adolor Clinical Research Associate who was directly accountable for the initiation and monitoring of Study 302. Confidential Witness One claims that after Study 302 was underway, three Adolor scientists commented that "the simple hysterectomy market segment was no longer viable for alvimopan, on the basis of interim '302' results." (Am. Compl. ¶ 39.) Based on the description of Confidential Witness One in the Amended Complaint, it is not clear how he or she would possess information regarding Defendants' knowledge or intent. Moreover, Confidential Witness One does not claim that Individual Defendants were aware of the scientists' comments prior to making public statements concerning the Phase III trials. Confidential Witness One also claims that Adolor's scientists received "unblinded" data packets from each study center, marked by study site number, principal investigator, and site coordinator, but again does not offer information suggesting that the Individual Defendants knew of this.

Confidential Witness Two is an administrative assistant employed by Adolor during the Class Period and unlikely to have information regarding Defendants' knowledge or state of mind. Confidential Witness Two claims that Defendants learned of all of the problems with Study 302 and Study 313 in a series of closed door meetings held just prior to issuing their public statements concerning Study 313 on September 23, 2003. However, Plaintiffs do not allege that Confidential Witness Two was present for any of the meetings or that Confidential Witness Two has first- or second-hand knowledge of what was discussed. Thus, the information provided by Confidential Witness Two lacks the requisite detail to satisfy Plaintiffs' burden of pleading with specificity.

Confidential Witness Three is a clinical program manager employed by Adolor. Confidential Witness Three claims that Defendants should have realized that simple hysterectomy patients should have been excluded from Study 308 based on information learned about this particular subgroup during Study 302, a point Confidential Witness Three emphasized by stating: "I'll bet the people at Glaxo went nuts when they found out they [simple hysterectomy patients] were included in the 308 test." (Am. Compl. ¶ 50(b).) What Defendants should have done regarding the Phase III trials is irrelevant to whether Defendants acted with the intent to deceive. As with the information provided by Confidential Witnesses One and Two, the information provided by Confidential Witness Three is not persuasive in determining Defendants' knowledge or intent.

Reliability and persuasiveness of the information provided by the confidential witnesses aside, Plaintiffs' allegations based on information provided by confidential witnesses, whether taken individually or together, fail to create the kind of detailed picture that is required to

establish scienter under the PSLRA. The information provided by the confidential witnesses does not illuminate Defendants' states of mind in connection with the statements at issue.

Finally, Plaintiffs can satisfy the scienter requirement by alleging facts demonstrating "strong circumstantial evidence of conscious misbehavior or recklessness." *Oran*, 226 F.2d at 288-89.[22] "A reckless statement is one 'involving not merely simple, or even inexcusable negligence, but an extreme departure from the standards of ordinary care, and which presents a danger of misleading buyers or sellers that is either known to the defendant or is so obvious that the actor must have been aware of it." *In re Advanta*, 180 F.3d at 535 (*citing McLean v. Alexander*, 599 F.2d 1190, 1192 (3d Cir. 1979)); *see also In re Digital Island*, 357 F.3d at 332 (*citing In re Adventa*, 180 F.3d at 535). When read in conjunction with Adolor's press releases, conference call transcripts, and SEC filings, the allegations in the Amended Complaint demonstrate that Defendants' public disclosures accurately described the results of each study. Furthermore, the Amended Complaint fails to allege facts demonstrating that Defendants had knowledge that would have made these statements false. Thus, there was no conscious misbehavior and no extreme departure from the standard of care that created a danger of misleading purchasers of Adolor stock.

We will not second guess the methodology employed by Defendants during the Phase III trial, regardless of whether Plaintiffs agree with Defendants' interpretation of the FDA

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[22] In *Tellabs*, the Supreme Court specifically stated that it has reserved the question of whether reckless behavior is sufficient for civil liability under Rule 10b-5 and would not address the issue in that case. *Tellabs*, 127 S. Ct. at 2507 n.3. However, the Court went on to recognize that every Court of Appeals, including the Third Circuit, allows a plaintiff to meet the scienter requirement by showing that a defendant acted recklessly.

guidelines. Defendants' public statements concerning the "randomized" or "double-blind" nature of the studies were not necessarily inconsistent with what actually occurred, let alone reckless. As the court noted in *Padnes*,

> [t]he securities laws do not impose a requirement that companies report only information from optimal studies, even if scientists could agree on what is optimal. Nor do they require that companies who report information from imperfect studies include disclosures of procedures used, including alternatives that were not utilized and various opinions with respect to those choices on the interpretation of the outcome of the data.

1996 WL 539711, at *5.

For the foregoing reasons, we find that Plaintiffs fail to allege facts showing that Defendants acted either recklessly or with intent to defraud when making statements concerning the Phase III trials.

B. Section 20(a) Claims

In addition to their Rule 10b-5 claims, Plaintiffs assert violations by controlling persons under Section 20(a) of the 1934 Act, 15 U.S.C. § 78t(a). In order to establish a Section 20(a) violation, plaintiffs must plead facts showing (1) an underlying violation by the company; and (2) circumstances establishing the defendant's control over the company's actions. *Majer v. Sonex Research, Inc.*, No. 05-606, 2006 WL 2038604, at *9 n.10 (E.D. Pa. July 19, 2006). Since we conclude that Plaintiffs failed to establish that Adolor violated Rule 10b-5, Plaintiffs' Section 20(a) claims must be dismissed. *See In re Merck & Co. Sec. Litig.*, 432 F.3d 261, 276-77 (3d Cir. 2005) (dismissing Section 20(a) claim where the plaintiff had failed to sufficiently allege violation of Section 10(b)); *Shapiro v. UJB Fin. Corp.*, 964 F.2d 272, 279 (3d Cir. 1992) (holding that "the dismissal of the § 10(b) claims against [the defendant corporation] made it

impossible to hold the individual defendants liable under § 20(a)"), *cert. denied*, 506 U.S. 934 (1992).

C. Section 11 Claims

Plaintiffs allege that Defendants are liable under Section 11 of the Securities Act because Adolor's Offering Prospectus contained false or misleading statements. Defendants contend that Plaintiffs' claims should be dismissed because (1) they are time-barred under the one-year statute of limitations, and (2) because Adolor's Offering Prospectus was neither false nor misleading. Section 11 is a "virtually absolute liability provision[ ], which do[es] not require plaintiffs to allege that defendants possessed any scienter." *In re Adams Golf*, 381 F.3d at 274 n.7. "If a plaintiff purchased a security issued pursuant to a registration statement, he need only show a material misstatement or omission to establish his prima facie case." *Herman & MacLean v. Huddleston*, 459 U.S. 375, 382 (1983). Under Section 11,

> a private action for damages may be brought "by any person acquiring such security" if a registration statement, as of its effective date: (1) "contained an untrue statement of material fact"; (2) "omitted to state a material fact required to be stated therein"; or (3) omitted to state a material fact "necessary to make the statements therein not misleading."

Chubb, 394 F.3d at 167 (*quoting* 15 U.S.C. § 77k(a)).[23] Section 11 claims can be premised on material misstatements absent fraud, mistake, or negligence and, accordingly, they need not comply with Rule 9(b)'s heightened pleading requirements. *Chubb*, 394 F.3d at 161 (noting that

[23] Section 11 "was designed to assure compliance with the disclosure provisions of the [Securities] Act by imposing a stringent standard of liability on the parties who play a direct role in a registered offering." *Huddleston*, 459 U.S. at 381-82 (footnote omitted). A Section 11 claim may be brought against the issuer of securities, its directors or partners, underwriters, and accountants who prepared or certified the registration statement. *Id.* at 382 n.13 (*citing* § 77k(a)).

"neither fraud, mistake, or negligence is required to plead a prima facie section 11 claim"); *In re Adams Golf*, 381 F.3d at 274 n.5 ("Claims under the 1933 Act that do not sound in fraud are not held to the heightened pleading requirements of [Rule] 9(b)."). However, Section 11 claims that sound in fraud must comply with Rule 9(b). *Chubb*, 394 F.3d at 161 (discussing why heightened pleading applies to Section 11 claims grounded in fraud).

Section 11 claims "must be brought within one year after the discovery of the untrue statement or the omission, or after such discovery should have been made by the exercise of reasonable diligence . . . ." 15 U.S.C. § 77m. "The limitations period begins to run when the plaintiffs have actual notice of the misstatement or omission giving rise to the cause of action, or . . . when the plaintiffs are placed on 'inquiry' notice of such culpable behavior." *Benak v. Alliance Capital Mgmt., L.P.*, 349 F. Supp. 2d 882, 887 (D.N.J. 2004) (*citing In re NAHC, Inc. Sec. Litig.*, 306 F.3d 1314, 1325 (3d Cir. 2002)), *aff'd*, 435 F.3d 396 (3d Cir. 2006).

Plaintiffs filed their Section 11 claim in a timely fashion. Under the "inquiry notice" standard, the one-year statute of limitations period begins to run when the plaintiffs "discovered or in the exercise of reasonable diligence should have discovered the basis for their claim" against the defendant. *Gruber v. Price Waterhouse*, 697 F. Supp. 859, 863 (E.D. Pa. 1988) (*citing Hobson v. Wilson*, 737 F.2d 1, 34 n.103 (D.C. Cir. 1984)), *aff'd*, 911 F.2d 960 (3d Cir. 1990). Plaintiffs filed their Section 11 claim on February 28, 2005. Defendants argue that the statute of limitations began to run on January 13, 2004, the day Adolor released the results from Study 308 because Plaintiffs have based their Rule 10b-5 claims in large part on statements made surrounding those results. We disagree. Although Plaintiffs' Rule 10b-5 claims are based partly on Defendants' public statements concerning Study 308, the alleged fraud would likely have

come to light only after the negative analyst reports were issued and Glaxo's European study results were released. We therefore must decide whether the Amended Complaint states a Section 11 claim.

In the Amended Complaint, Plaintiffs "disclaim any allegations of fraud" for purposes of their Section 11 claim. (Am. Compl. ¶ 81.) Plaintiffs' disclaimer, however, does not automatically remove their Section 11 claim from Rule 9(b)'s heightened pleading standard. *See Chubb*, 394 F.3d at 161 & n.24 (applying Rule 9(b)'s heightened pleading requirements to the plaintiffs' Section 11 claim despite disavowal paragraph in the Section 11 count of the complaint stating that the "[p]laintiffs expressly disclaim any allegations of fraud, knowledge, intent, or scienter"). The Third Circuit has instructed that, notwithstanding artful pleading,[24] the proper analysis for determining whether Rule 9(b) applies to a Section 11 claim is to "'examine the factual allegations that support [the] legal claim'" to see if they are based on fraud. *See id.* (*quoting Shapiro*, 964 F.2d at 288). For the reasons set out in our discussion of the misrepresentation element of Plaintiffs' Rule 10b-5 claim, we do not believe that Plaintiffs have alleged facts demonstrating that statements made by Defendants were false or omitted material facts. The allegations in the Amended Complaint on their face, and not the heightened specificity required by Rule 9(b), lead to that conclusion. Thus, Plaintiffs cannot state a claim regardless of the outcome of the *Chubb* analysis.

In any event, an analysis under *Chubb* requires the application of Rule 9(b)'s heightened

[24] We note that Plaintiffs' current counsel also represented the plaintiffs in *Chubb* before the Third Circuit. 394 F.3d at 133-34. The opinion in *Chubb* was issued approximately five months before Plaintiffs filed the instant Amended Complaint.

pleading standard to Plaintiffs' Section 11 claim. *See id.* Although Plaintiffs have sanitized Count III – the Section 11 claim – of the Amended Complaint to exclude all allegations of fraud (*see* Am. Compl. ¶¶ 80-87), Plaintiffs allegations, read together, "reveal[] that a core theory of fraud permeates" the Amended Complaint. *See Chubb*, 394 F.3d at 161. Count III incorporates paragraphs 29 to 79 of the Amended Complaint, which allege, *inter alia*, that Defendants engaged in a scheme to defraud not only investors but also the FDA by manipulating the Entereg Phase III trials and by controlling what information regarding the Entereg Phase III trials was revealed to the public. In addition, since we determined that Defendants had no duty to disclose the information that Plaintiffs allege was material, Plaintiffs cannot state a Section 11 claim premised on those omissions. *See In re Adams Golf*, 381 F.3d at 277 (noting that in order to state a Section 11 claim based on material omissions, there must be an underlying duty to disclose).

IV. CONCLUSION

For the foregoing reasons, we conclude that the Amended Complaint fails to properly state claims upon which relief can be granted. Accordingly, Defendants' Motion will be granted and Plaintiffs' Amended Complaint will be dismissed.

An appropriate Order will follow.

BY THE COURT:

R. Barclay Surrick, Judge